Amendment
Attorney Docket No. H01.2I-11733-US01

Amendments To The Drawings:

Attached is a proposed new Figure 1. The new figure is fully supported by claim 14 as filed and the specification as filed, and merely conforms the specification and drawings to the claims as filed.

Applicant will file a formal replacement sheet once this proposed figure is approved.

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Remarks

This Amendment is in response to the Office Action dated **December 16, 2005.**In the office action, the Examiner required that the drawings show the syringe of claim 14 or that claim 14 be cancelled; rejected claims 1-3, 5 and 9-13 as anticipated by Jensen US 6048202; rejected claims 1-5 and 9-13 as anticipated by Dragan US 5676543; rejected claims 6-8 and 14 as obvious over Jensen, and rejected claims 6-8 and 14 as obvious over Dragan.

Objection To The Drawings

Applicant has attached a proposed Figure 1 to this amendment, and amended the specification accordingly. There is no new matter, as both the figure and the amendment to the specification merely conform the application to claim 14 as filed. In other words, all of the structure shown in Figure 1 and discussed in the amended specification was already fully disclosed in original claim 14.

Anticipation Rejections

Both independent claims 1 and 10 have been amended to incorporate the limitation of claim 4, that the <u>covering composition is selected from the group consisting of A-silicones</u>.

Therefore, claim 4 has been cancelled.

The citation US 5,676,543 (Dragan) describes a device for taking a tooth impression under retraction of the gum in preparation for tooth crowns, bridges and similar restorations. The Dragan reference includes the following steps:

- Creating the tooth core (It is important that the gingiva is removed as far as possible from the core to ensure an accurate fit of the future crown.).
- Use of a high viscosity "heavy body putty type moldable material" with the hand (with rubber gloves) or a tray for creating an approximate impression of the core (the so-called "first impression").

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- A flowable second silicone "less viscous flowable material" is poured into the approximate impression and both are pressed together onto the tooth core again. The flowable revision material takes the place of the retraction cord and reproduces the portion of the core that borders the sulcus (the so-called "revision impression").

The complete sentence in column 4, paragraph 3 from Dragan that characterizes the material as isolating material reads as follows:

"Fig. 6 illustrates the patient exerting a slight pressure on the mold material 10 assuring that the flowable material 18 is forced between the teeth 12, 12 and gum 14. The mold material 10, acting like a dam, causes the flowable material 18 to exert pressure along the gingival line forming a sulcus, groove or trough."

This means that the patient exerts light pressure on the high viscous cured initial silicone with light contact of the upper dental arch on the first impression so that the low viscosity silicone can flow into the sulcus and accurately form an impression.

The first impression serves as a dam in the process which secures that the gingiva is pressed back and that the second flowable silicone flows into the gingiva. The first impression, however, does not have anything more to do with the recording protective layer material because it is not a flowable or spreadable material that can either be applied to the adjacent gingiva and bonded to the gingiva after curing. The high viscosity material can only be applied by hand or with an impression tray, but cannot be applied with a cartridge due to its poor flowability like the patented recording protective layer. A barrier effect is described in the patent script only for the method involving the patient's teeth pressing the first impression against the gingiva, but not for a highly viscous material that is applied to the teeth and cured.

Additionally, US 5,676,543 indicates the preferred use of a condensation silicone and discourages the use of A-silicones (column 3, line 24 et. seq.). Furthermore, it is not stated anywhere in the US document that the materials should adhere to the gingiva. In contrast, the

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materials should preferably not adhere to the gingiva, since they impair the precision of the impression.

Thus, the solution to the problem solved by the present invention does not have the slightest to do with the contents of the Dragan US 5,676,543 document.

The contents of the citation US 6,048,202 (Jensen et al.) were extensively discussed in our application (US 6,305,936 page 2, paragraph 2 et. seq.). They represent the next state of technology. We have solved the task of devising a method and manufacturing an isolation device for the tooth substance and/or protection from the dental treatment mediums for the surrounding gingiva and/or neighboring teeth. We have made a device and created a method that is, in contrast to US 6,048,202, faster to apply, more comfortable and less toxic to the patient during application based on this patent specification.

The adhesion during relative drying of the operating field is surprisingly achieved with the help of cotton rolls and an air syringe according to the proposed patent protective layer material. A silicone polymer is present that contains vinyl functions as reactive lateral chains and a platinum catalyst in the A component of the A-silicones to be used. The B component contains a cross-linking agent and polymer with vinyl groups is added until the desired mixing ratio is obtained. The chemistry of curing proceeds over the direct connection between a Si-H function of the cross-linker to the polymer vinyl function. An ethylene bridge is formed at each cross-linking point, thus forming a Si-C-C-Si link.

The C silicones contain a silanol in the A component, thus a silicone polymer with a Si-OH end group, and a cross-link that carries the end group that can be hydrolyzed. The B components contain the catalyst and, as a rule, a liquid silicone that do not carry functional groups. The curing mechanism proceeds in such a way that the cross-linker releases a

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decomposition product, mostly pure alcohol and then condenses with the silanol. A siloxane bridge forms at this junction for each cross-linking point, thus a Si-O link is formed.

These differences in the cross-linking make several things clear:

- a.) Cross-linked A silicones are more hydrophobic than cross-linked C silicones due to the cross-linking between Si-C and Si-O. Therefore, in comparison to hydrophilic treatment agents like bleaching and etching mediums, A silicones have a sealing effect different from the C silicones.
- b.) Using A silicones presents a major application advantage. These products are not susceptible to hydrolysis and, therefore, can be store without losing their stability. If humidity comes in contact with the C silicone component, the cross-linker hydrolyzes and immediately condenses with the silanol. This is the reason that C silicone must be extremely well packaged in order to guarantee the stability of the product.

No person of ordinary skill in the art could infer a reference to US 5,676,543 from the proposed protective layer material of the current patent application. This document exclusively provides information regarding impression materials and does not give any consideration to adhesion of materials to the gums. None of the materials listed in the patent are suitable as a bonding material for the gums.

Likewise, no person of ordinary skill in the art could infer a reference to US 6,048,202 from the proposed protective layer material of the current patent application. This document formed the starting point for the patent application material. It describes the method of light-initiated radical polymerization of modified acrylate to seal the soft tissue areas.

Therefore, it is believed that claims 1-3 and 5-14, as amended distinguish over the cited references, and are therefore neither anticipated or obvious in view of the cited art.

Allowance of claims 1-3 and 5-14 is respectfully requested.

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Respectfully submitted,

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